DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 12, 2014

Advanced Nuclide Technologies, LLC
% Sergey Baklanov, Ph.D.
President
21756 Green Stable Sqare, #309
ASHBURN VA 20147

Re: K141038
Trade/Device Name: ANT Model 1
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: November 3, 2014
Received: November 6, 2014

Dear Dr. Baklanov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141038

Device Name
Advanced Nuclide Technologies LLC (ANT) Model 1 Brachytherapy Source

Indications for Use *(Describe)*
Advanced Nuclide Technologies LLC (ANT) Model 1 Brachytherapy Sources, with individual activities up to 5 mCi (185 MBq), are indicated for temporary or permanent interstitial, intracavitary, intraluminal or intraoperative implantation or surface application to treat selected localized tumors. They can be used either as primary treatment for unresectable tumors, or as treatment for residual disease after excision of primary or recurrent tumors such as for lung cancer. ANT Model 1 Brachytherapy Source may be used concurrently with or following treatment with other interventions, such as external beam therapy, or chemotherapy. Tumors of the head, neck, lung, pancreas, prostate, breast and other accessible tumors are commonly treated.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Section 807.92(a)

(1) Submitter

Advanced Nuclide Technologies, LLC
21756, Green Stable Sq., #309
Ashburn, VA 20147

t: 267.253.2271

Establishment Registration No.: To Be Applied For

Contact Person: Sergey Baklanov, Ph. D., President
e-mail: Sergey_RMC@msn.com

Date Prepared: 18 June 2014

(2) Device Name:

Classification Name: Radionuclide Brachytherapy Source (892.5730) (90 KXK)

Common or Usual Name: Brachytherapy Source

Proprietary Name: ANT Model 1

(3) Legally Marketed Predicate Devices:

Implant Sciences Corp. I-Plant Model 3500 (^{125}Iodine Brachytherapy Seed) cleared under 510(k) number K994317 dated 21 March 2000

and

Source Production & Equipment Co., Inc. Model M-31, cleared under 510(k) number K090366 dated 22 April 2009

(4) Description of ANT Model 1 Brachytherapy Source:

ANT Model 1 is a singly-encapsulated Brachytherapy Source. It consists of a titanium capsule containing a solid radioactive material. There are two versions of the ANT Model 1. The ANT Model 1 Type-Y contains a solid ^{169}Ytterbium pellet. The ANT Model 1 Type-I contains a solid nonradioactive Ytterbium pellet onto which is plated radioactive ^{125}Iodine. In both cases, the capsule which contains the pellet consists of a deep-drawn titanium can which is closed on the end with a titanium plug which is laser-welded to the can.

The ANT Model 1 Brachytherapy Source emits gamma rays and characteristic x-rays from the decay of the respective radionuclides.

(5) Intended Use

The intended use of ANT Model 1 Brachytherapy Source is for the treatment of cancer by temporary or permanent interstitial, intracavitary, intraluminal or intraoperative implantation or surface application.

(6) Technological Characteristics:

The ANT Model 1 Brachytherapy Source is similar to the predicate low dose rate brachytherapy source and utilizes photons from either ^{169}Ytterbium or ^{125}Iodine.

Technological Characteristic	**Advanced Nuclide Technologies, LLC (ANT) Model 1 Brachytherapy Source**	**Source Production & Equipment Co., Inc. (SPEC) M-31 ^{169}Ytterbium Brachytherapy Source K090366**	**Implant Sciences Corp. I-Plant Model 3500 (^{125}Iodine Brachytherapy Seed) K994317**
Design	The source consists of a solid Ytterbium rod (0.5 mm dia x 3.0 mm long) singly encapsulated. The capsule (0.85 mm dia x 4.5 mm long) is titanium. The capsule is seal welded.	The source consists of a solid ^{169}Ytterbium rod (0.25 mm dia x 1.25 mm long) singly encapsulated. The capsule (0.42 mm dia x 5.1 mm long) is titanium. The capsule is seal welded.	I-Plant Model 3500 (^{125}Iodine Brachytherapy Seed) consists of a laser-welded titanium capsule containing a silica tube that serves as a substrate for the radioactive ^{125}Iodine source. The tube is positioned around a silver radiopaque x-ray marker that identifies the source location and orientation. The seeds are provided non-sterile.
Materials Radionuclide Encapsulation	^{169}Ytterbium OR ^{125}Iodine Titanium (Medical Grade)	^{169}Ytterbium Titanium (Medical Grade)	^{125}Iodine Titanium (Medical Grade)
Performance Dosimetry (TG43) Dose Rate Const (λ) Anisotropy (ϕ_{av}): Radial Dose Fn:	 (^{169}Yb): 1.20 cGy h^{-1} U^{-1} (^{125}I): 1.00 cGy h^{-1} U^{-1} (^{169}Yb): 0.95 (^{125}I): 0.93 Shown in Figure 1	 1.24 cGy h^{-1} U^{-1} 0.99 Shown in Figure 1[1]	 1.01 cGy h^{-1} U^{-1} 0.95 Shown in Figure 1[2]
Sterility	Sources are non-sterile when shipped. Sources are sterilized by the user.	Sources are non-sterile when shipped. Sources are sterilized by the user.	Seeds are non-sterile when shipped. Seeds are sterilized by the user.
Biocompatibility	The outer encapsulation of the ANT Model 1 Brachytherapy Source is medical grade titanium, which has been determined to be biocompatible in a large number of medical devices.	The outer encapsulation of the SPEC M31 ^{169}Ytterbium Brachytherapy Source is medical grade titanium, which has been determined to be biocompatible in a large number of medical devices.	The outer encapsulation of the I-Plant Model 3500 (^{125}Iodine Brachytherapy Seed) is medical grade titanium, which has been determined to be biocompatible in a large number of medical devices.
Mechanical Safety	ANSI N43.6 Class C54212	ANSI N43.6 Class C54212	ANSI N43.6 Class C54213
Energy Delivered	For the ANT Model 1 Type-Y: ^{169}Ytterbium (half-life: 32.02 days) which decays by electron capture with the emission of characteristic photons and electrons. The electrons are absorbed by the titanium wall of the source encapsulation. The principal photon emissions are 50, 51, 57 and 59 keV x-rays and a	^{169}Ytterbium (half-life: 32.02 days) which decays by electron capture with the emission of characteristic photons and electrons. The electrons are absorbed by the titanium wall of the source encapsulation. The principal photon emissions are 50, 51, 57 and 59 keV x-rays and a 63, 94, 110, 118, 131, 177,	^{125}Iodine (half-life: 59.43 days) which decays by electron capture with the emission of characteristic photons and electrons. The electrons are absorbed by the titanium wall of the seed. The principal photon emissions are 27.4 and 31.4 keV x-rays and a 35.5 keV gamma. Also emitted are 22.1 and 25.2 keV

	63, 94, 110, 118, 131, 177, 198, 261 and 308 keV gammas. For the ANT Model 1 Type-I: ^{125}Iodine (half-life: 59.43 days) which decays by electron capture with the emission of characteristic photons and electrons. The electrons are absorbed by the titanium wall of the source. The principal photon emissions are 27.4 and 31.4 keV x-rays and a 35.5 keV gamma. Also emitted are 22.1 and 25.2 keV fluorescent x-rays from the silver substrate.	198, 261 and 308 keV gammas.	fluorescent x-rays from the silver marker.
Compatibility with Environment and Other Devices	^{169}Ytterbium and ^{125}Iodine are radioactive materials and should be strictly controlled. If any source cannot be accounted for, the loss should be reported to the federal or state licensing agency. The source should only be used following the conditions and limitations specified by the licensing authority (NRC or Agreement State). The source should be stored in a shielded container, either the transport container in which it is delivered or other suitable container. Store at normal room temperature. When disposal is indicated, radioactive material should be transferred to an authorized recipient, typically the source supplier. Radioactive material should never be disposed of in normal waste.	^{169}Ytterbium is a radioactive material and should be strictly controlled. The source should only be used following the conditions and limitations specified by the licensing authority (NRC or Agreement State). The source should be stored in a shielded container, either the transport container in which it is delivered or other suitable container. If any source cannot be accounted for, the loss should be reported to the federal or state licensing agency. Store at normal room temperature. When disposal is indicated, radioactive material should be transferred to an authorized recipient, typically the source supplier. Radioactive material should never be disposed of in normal waste.	^{125}Iodine is a radioactive material and should be strictly controlled. If any significant material cannot be accounted for, the loss should be reported to the federal or state licensing agency. When disposal is indicated, radioactive material should be transferred to an authorized radioactive waste disposal agency. Radioactive material should never be disposed of in normal waste.
Where Used	ANT Model 1 Brachytherapy Source is designed to be opened and used in the operating room.	SPEC Model M31 Brachytherapy Source is designed to be opened and used in the operating room.	I-Plant Model 3500 (^{125}Iodine Brachytherapy Seed) is designed to be opened and used in the operating room.
Standards Met Mechanical Dosimetry	 ANSI N43.6 AAPM TG-43	 ANSI N43.6 AAPM TG-43	 ANSI N43.6 AAPM TG-43
Electrical Safety	Not Applicable	Not Applicable	Not Applicable

Thermal Safety	Not Applicable	Not Applicable	Not Applicable
Radiation Safety	These ^{169}Ytterbium and ^{125}Iodine sources are radioactive, and appropriate precautions must be taken during handling to minimize radiation exposure to personnel. Personnel monitoring is required. This sources should be handled with as much distance as practical between sources and the operator. Any manipulation of ANT Model 1 sources should be carried out behind shielding of adequate thickness. The first half value thickness of lead for ^{169}Ytterbium is 0.25 mm. A 6.7 mm lead sheet will provide >99% reduction in exposure. The half value thickness of lead for ^{125}Iodine is 0.025 mm. Thus, a 0.25 mm lead sheet will provide >99% reduction in exposure.	This ^{169}Ytterbium source is radioactive, and appropriate precautions must be taken during handling to minimize radiation exposure to personnel. Personnel monitoring is required. This source should be handled with as much distance as practical between sources and the operator. Any manipulation of SPEC Model M31 sources should be carried out behind shielding of adequate thickness. The first half value thickness of lead for ^{169}Ytterbium is 0.25 mm. A 6.7 mm lead sheet will provide >99% reduction in exposure.	I-Plant Model 3500 (^{125}Iodine Brachytherapy Seed) is radioactive, and appropriate precautions must be taken during handling to minimize radiation exposure to personnel. Personnel monitoring is required. I-Plant Model 3500 (^{125}Iodine Brachytherapy Seed) should be handled with forceps only and with as much distance as practical between seeds and the operator. Any manipulation of I-Plant Model 3500 (^{125}Iodine Brachytherapy Seed) should be carried out behind shielding of adequate thickness. The half value thickness of lead for ^{125}Iodine is 0.025 mm. Thus, a 0.25 mm lead sheet will provide >99% reduction in exposure.

Section 807.92(b)

(1) Nonclinical Tests

Physical Testing

The ANT Model 1 source has been subjected to the tests specified in American National Standard (ANSI) N43.6 and International Organization for Standardization (ISO) Standard 2919, as referenced in the FDA "Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources" dated 2 August 2000.

Prototype sources were subjected to the tests specified in ANSI N43.6-2007 and ISO 2919-2012 and have equaled or exceeded the requirements corresponding to a classification of C53211, which is the requirement for brachytherapy sources. This is equivalent to the physical testing of the predicate devices.

Dosimetry

The dose distribution around the ANT Model 1 source was calculated by Monte Carlo simulation in accordance with the recommendations of the American Association of Physicists in Medicine and the European Society for Therapeutic Radiation Oncology.[3] This is equivalent to the dosimetry of the predicate devices.

(2) Clinical Tests

Not Applicable

(3) Conclusions

The results of the nonclinical physical tests and the dosimetric analysis, demonstrate that the ANT Model 1 Brachytherapy Source is as safe, as effective, and performs as well or better than the legally marketed predicate devices:

Implant Sciences Corp. I-Plant Model 3500 (^{125}Iodine Brachytherapy Seed) cleared under 510(k) number K994317 dated 21 March 2000

and

Source Production & Equipment Co., Inc. Model M-31, cleared under 510(k) number K090366 dated 22 April 2009

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[1] Currier B, Munro JJ and Medich DC, Dosimetric characterization of the GammaClip™ 169Yb low dose rate permanent implant brachytherapy source for the treatment of nonsmall cell lung cancer postwedge resection, Med Phys. 2013 Aug;40(8):080701

[2] Duggan DM, Johnson BL, "Dosimetry of the I-Plant Model 3500 iodine-125 brachytherapy source", Med Phys 2001 Apr;28(4):661-70

[3] Perez-Calatayud J, Ballester F, Das RK, Dewerd LA, Ibbott GS, Meigooni AS, Ouhib Z, Rivard MJ, Sloboda RS, Williamson JF, Dose calculation for photon-emitting brachytherapy sources with average energy higher than 50 keV: report of the AAPM and ESTRO, Med Phys. 2012 May;39(5):2904-29